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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
Office Action Summary	10/808,142	STEIN ET AL.
	Examiner	Art Unit	
	Stephen Alvesteffer	2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-40 and 42-92* is/are pending in the application.
    4a) Of the above claim(s) *44,48-57 and 65-81* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-21,23-40,42,43,45-47,58-64 and 82-92* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All   b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is responsive to the Request for Continued Examination (RCE)

filed March 9, 2009. Claims 1-21, 23-40, 42, 43, 45-47, 58-64, and 82-92 are amended.

Claims 22 and 41 are cancelled. Claims 44, 48-57, and 65-81 are withdrawn from

consideration. Claims 1, 46, 47, 58, 82, and 92 are independent. Claims 1-21, 23-40,

and 42-92 remain pending.

Claim Objections

Claim 82 is objected to because of the following informalities: The limitations of

collating, recording, automatically generating, enabling, and communicating each use a

programmed computer, but it is unclear whether each limitation is uses the same

programmed computer or several different programmed computers. Appropriate

correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of
making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the
art to which it pertains, or with which it is most nearly connected, to make and use the same and shall
set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 23-40, 42, 43, 45-47, 58-64 and 82-92 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed

invention.

Independent claims 1, 46, 47, 58, 82, and 92 recite a "*navigation means being*

further arranged to permit the healthcare practitioner to traverse a route across the map

*that **misses out one or more nodes** from the series of nodes representing a currently*

traversed patient care pathway" (emphasis added). The section of the limitation reciting

"misses out one or more nodes" is not in the specification and its meaning is unclear. It

is noted that the instant Specification paragraph [0131] does disclose "[i]n some cases,

it may also be possible for the clinical practitioner to **skip certain nodes**" (emphasis

added). Because the terminology of "misses out one or more nodes" is not in the

specification, it must be interpreted with the broadest reasonable interpretation in light of

the specification. The meaning of "misses out a node" remains unclear and Applicant is

urged to use the terminology in the Specification, such as "skip one or more nodes".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

Independent claims 1, 46, 58, 92, and their dependent claims are rejected under

35 U.S.C. 112, second paragraph, for using improper means plus function language.

The claim limitations "data entry means for entering clinical data" and "editing

means for enabling the healthcare practitioner to edit at least some of the nodes on the

page" use the phrase "means for" or "step for", but are modified by some structure,

material, or acts recited in the claim. It is unclear whether the recited structure,

material, or acts are sufficient for performing the claimed function which would preclude

application of 35 U.S.C. 112, sixth paragraph, because the data entry means is recited

as comprising a display means.

If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth

paragraph, applicant is required to amend the claim so that the phrase "means for" or

"step for" is clearly **not** modified by sufficient structure, material, or acts for performing

the claimed function.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C.

112, sixth paragraph, applicant is required to amend the claim so that it will clearly not

be a means (or step) plus function limitation (e.g., deleting the phrase "means for" or

"step for").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

Claims 1-7, 11-16, 20, 21, 23, 24, 35-37, 39-43, 45-47, 58-64, 82-85, and 87-92

rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae et al. (hereinafter

Macrae), United States Patent 5,786,816, and Campbell et al. (hereinafter Campbell),

United States Patent 6,047,259.

Regarding claim 1, Macrae teaches a programmed computer comprising a

processor configured to assist a healthcare practitioner in diagnosing and treating

patients by interacting with the healthcare practitioner during progression through a

stored clinical best practice workflow comprised of a plurality of interlinked steps (see

Macrae column 1 lines 6-11; "*The present invention relates to providing graphic medical*

healthcare plans (protocols), and in particular a graphic user interface, for developing,

viewing and implementing medical healthcare plans"), the programmed computer

comprising:

a page including a map for assisting the healthcare practitioner to navigate the

stored clinical best practice workflow, the map comprising a plurality of patient care

pathways, each patient care pathway conforming with best practice guidelines and

comprising a series of a plurality of interlinked nodes, wherein each node in the series

has a unique relationship with a respective step in the stored best practice workflow

(see Macrae Figure 1 and column 6 lines 26-31; "*In Flow Chart view 11, the process*

flow begins with a Start node, enters into the first Order nodes, and flows out to Result

nodes. After the results are entered, the process flow continues on to a Flow Control

node where the next step in the treatment is determined");

data entry means for entering clinical data relating to a particular selected node,

the data entry means comprising display means for displaying, within a portion of the

page, a predetermined data entry request and a response made by the healthcare

practitioner to the request (see Macrae Figure 3 and column 6 line 53 through column 7

line 8; "*a user can start the flow, enter order result into the various nodes, and move*

through the flow as the treatment progresses using the Flow Chart view instead of the

Chart view if the user desires");

data recording means for storing the response, made by the healthcare

practitioner to the request, in a data record (see Macrae column 2 lines 44-55;

"*Processing means controls the storage means, input means and the display means in*

response to stored programs and input data");

pathway means arranged to use the response of the healthcare practitioner

stored in the data record to graphically indicate a suggested node to traverse next within

the stored best practice workflow (see Macrae column 7 lines 50-60; "*The Flow Control*

node contains rules that select a branch at a decision point in a template or plan, and

estimates of the likelihood of branching down given paths. During patient charting, the

Flow Control node suggests the next step to the healthcare provider based on the rules

and the results entered in Result nodes"; see also Macrae column 13 lines 20-30;

"*These connections indicate possible paths or branches a plan takes during delivery,
and are illustrated as arrows*");

navigation means arranged to enable the healthcare practitioner to choose the
node to traverse next independently of the node suggested by the pathway means, the
navigation means being further arranged to permit the healthcare practitioner to
traverse a route across the map that misses out one or more nodes from the series of
the plurality of interlinked nodes representing a currently traversed patient care pathway
(see Macrae column 19 lines 56-60; "*To force the plan to branch down a specific path,
regardless of the result values and the flow control rules, a user opens the right-most
active Flow Control node, select the rule governing the desired path, and click the
Execute button. The plan will branch down the specified path*"; see also Macrae column
12 lines 36-40; "*The Flow Control node contains the rules that determine which set of
orders are followed. Flow Control nodes are connected to one or more Order nodes.
However, only one of the Order nodes will be executed*");

graphical means for graphically representing in the page a route traversed by the
healthcare practitioner across the map (see Macrae column 19 lines 36-44; "*When a
user takes a branch down a path that leads to a Plan node in the patient's chart, the
Plan node is highlighted in both the Flow Chart and the patient Chart views*"; see also
Macrae column 6 line 53 through column 7 line 8; "*a user can start the flow, enter order
result into the various nodes, and move through the flow as the treatment progresses
using the Flow Chart view instead of the Chart view if the user desires. Color-coding on
the nodes show which ones are completed and which are in progress*"); and

Electronic Patient Record Management System (EPRMS) management means for communicating with an EPRMS and obtaining and presenting details of a selected electronic patient record in a portion of the page (Campbell, addressed below).

Macrae teaches does not explicitly disclose Electronic Patient Record Management System (EPRMS) management means for communicating with an EPRMS and obtaining and presenting details of a selected electronic patient record in a portion of the page. Campbell teaches an interactive diagnosis and treatment system that accesses electronic patient records stored on a server (see Campbell column 14 lines 19-29; "*When the user selects a screen for display, the patient data in the display is drawn from the current patient records on the server*"). It would have been obvious to one of ordinary skill in the art at the time the invention was made to access patient record information as taught by Campbell in the invention of Macrae so that healthcare practitioners do not have to re-enter data that is already accessible electronically.

Regarding claim 2, Macrae/Campbell teaches that the plurality of patient care pathways represent a complete stored clinical best practice workflow on a single page (see Macrae Figure 1).

Regarding claim 3, Macrae/Campbell teaches that each node represents an action, decision or result within the stored clinical best practice workflow (see Macrae column 7 lines 27-34; "*There are five kinds of nodes: Start, Order, Results, Flow Control, and Exit*").

Regarding claim 4, Macrae/Campbell teaches that the data entry means comprises presentation means for presenting data relevant to a location of the selected

node and selection means for enabling the healthcare practitioner to select at least

some of that data (see Macrae column 11 line 28; "*Or1 node is selected by clicking it*").

Regarding claim 5, Macrae/Campbell teaches every limitation of claim 5 except

that the presentation means comprises a plurality of drop-down lists of location-specific

information. Although Macrae does not teach using a plurality of drop-down lists to edit

location-specific information, Macrae does disclose the use of drop-down lists (see

Macrae Figure 21 and column 14 lines 40-46; "*For this example, click the At Probability*

drop-down arrow button 213 and select 10 as the percentage"). Drop-down lists are a

standard user interface component for use in data entry. Macrae makes use of drop-

down lists in some instances. It would have been an obvious design choice for one of

ordinary skill in the art at the time the invention was made to use a plurality of drop-

down lists to edit location-specific information.

Regarding claim 6, Macrae/Campbell teaches that the data entry means is

arranged to use the entered data at a first node to determine further information

required at a second node, linked to the first node (see Macrae column 18 lines 48-53;

"*Each time an order result is entered, the rules in the Flow Control node are evaluated*

to see if enough information is available to branch to the next step in the plan. When all

of the order results specified in a rule are entered, the rule is evaluated. If the rule is

satisfied, the rule will become active and take the plan down the corresponding path").

Regarding claim 7, Macrae/Campbell teaches updating means for updating any

information related to the step in the stored clinical best practice workflow with entered

data (see Macrae column 9 lines 57 and 58; "*Edit button 119 edits the detail of the selected order, including the order's result values when clicking*").

Regarding claim 11, Macrae/Campbell teaches analyzing means for analyzing the entered data and generating a list of actions associated therewith and listing means for listing the list of associated actions to the healthcare practitioner adjacent the interlinked nodes (see Macrae Figure 2, showing the interlinked nodes and a list of actions with associated cost analysis at the bottom).

Regarding claim 12, Macrae/Campbell teaches that at least some of the nodes include information means providing a graphical indication that concealed clinical information relating to the step in the stored best practice workflow associated with that node is available for presentation on the page, the information means being arranged to reveal the concealed clinical information on selective interaction with the nodes by the healthcare practitioner (see Macrae column 6 lines 38-42; "*The Zoom view is used to see the details inside the nodes of the template. Each node is magnified or expanded to show information contained within, as well as the relationships between the nodes in the flow chart. A user can use this view to examine the entire template*").

Regarding claim 13, Macrae/Campbell teaches that the graphical indication is a graphical icon (see Macrae Figure 2).

Regarding claim 14, Macrae/Campbell teaches that the information means is arranged to provide a plurality of different levels of detail of information, in accordance with a selection made by the healthcare practitioner (see Macrae column 6 lines 38-42; "*The Zoom view is used to see the details inside the nodes of the template. Each node*

is magnified or expanded to show information contained within, as well as the

relationships between the nodes in the flow chart. A user can use this view to examine

the entire template").

Regarding claim 15, Macrae/Campbell teaches action list means for generating

a list of actions and presenting the same to the healthcare practitioner adjacent the

plurality of interlinked nodes, the action list means being arranged to determine the list

from analysis of the healthcare practitioner's navigation through the plurality of

interlinked nodes (see Macrae Figure 2, showing the plurality of displayed interlinked

nodes and a list of actions with associated cost analysis at the bottom).

Regarding claim 16, Macrae/Campbell teaches that the action list means is

arranged, at the end of traversal of the map, to present the list to the healthcare

practitioner with options for the healthcare practitioner to confirm each action, and to

determine the list of actions to be implemented from the healthcare practitioner's

confirmation (see Macrae Figure 2, showing the plurality of displayed interlinked nodes

and a list of actions with associated cost analysis at the bottom).

Regarding claim 20, Macrae/Campbell teaches a new page linking means for

linking a node at the end of a series of a plurality of interlinked nodes within one page to

a node within another different page (see Macrae Figure 23 and column 19 lines 45-51;

"*When a user charts a patient plan into a Plan node, the previous plan is discontinued*

and the new plan is started. The view of the new plan will be used to continue

charting").

Regarding claim 21, Macrae/Campbell teaches that the new page linking means comprises a graphical icon and selection by the healthcare practitioner comprises interaction between an end-user navigational tool and the icon (see Macrae Figure 23 and column 19 lines 45-51; *"When a user charts a patient plan into a Plan node, the previous plan is discontinued and the new plan is started. The view of the new plan will be used to continue charting"*).

Regarding claim 23, Macrae/Campbell teaches that the EPRMS management means further comprises population means for populating one or more nodes with at least some of the details of a selected electronic patient record, thereby reducing any required data entry at that node (see Campbell column 14 lines 19-29).

Regarding claim 24, Macrae/Campbell teaches that the EPRMS management means is arranged to use the details of the selected electronic patient record to determine what information is required at a node from the healthcare practitioner (see Campbell column 14 lines 30-35; *"When the user initiates the exam, the server evaluates the observations and determines which questions and warnings should be displayed to the user. As the user accesses screens in the exam, these warnings or questions form part of the display screen. Thus, the display changes based on prior recorded observations"*).

Regarding claim 35, Macrae/Campbell teaches editing means for editing the nodes on a page, the editing means being arranged to update the stored workflow to reflect any change made to the page (see Macrae Figure 1 and column 6 lines 14-25; *"FIG. 1 illustrates an example of a Template Builder window with an open template"*).

Regarding claim 36, Macrae/Campbell teaches that the editing means is arranged to enable the healthcare practitioner to add a new node and to specify the contents of the new node (see Macrae Figure 9 and column 8 lines 59-65; "*FIG. 9 illustrates adding an Order node Or1, Result node Re1 and Flow Control node Fl1 to a template*").

Regarding claim 37, Macrae/Campbell teaches that the editing means is arranged to enable the healthcare practitioner to specify functionality associated with a node (see Macrae column 8 lines 59-65; "*The Order node Or1 contains the physician's orders, such as lab tests, nursing procedures, x-rays, prescriptions, and other kinds of treatments or actions. These generalized orders may be taken from a library and placed in Order node Or1*").

Regarding claim 39, Macrae/Campbell teaches that the editing means is arranged to enable the healthcare practitioner to control the positioning of the new node within the page and interconnection of the new node to the existing nodes (see Macrae column 6 lines 14-25; "*The template contains a number of graphic elements including: a start node, three triplets of an order node, a result node, a flow control node and an exit node. These graphical elements are positioned in window 10 in order to represent a medical healthcare treatment plan*").

Regarding claim 40, Macrae/Campbell teaches recording means for recording the route traversed by the healthcare practitioner across the map (see Macrae column 6 lines 26-31; "*In Flow Chart view 11, the process flow begins with a Start node, enters into the first Order nodes, and flows out to Result nodes. After the results are entered,*"

the process flow continues on to a Flow Control node where the next step in the

treatment is determined").

Regarding claim 42, Macrae/Campbell teaches navigation analysis means,

wherein information relating to each step in the process is cost quantifiable and the

navigation analysis means is arranged to determine a total cost of the route traversed

by the healthcare practitioner (see Macrae column 2 lines 26-38; *"it is desirable to*

provide an apparatus and method for providing a medical healthcare plan which will 1)

reduce errors associated with communications between healthcare planners and

providers; 2) allow for convenient modification of medical health treatment plans; 3)

provide costs associated with each step in the medical health treatment plan, as well as

the total cost of the medical health treatment plan").

Regarding claim 43, Macrae/Campbell teaches that the navigation analysis

means is arranged to analyse the performance of the healthcare practitioner through the

stored best practice workflow (see Macrae column 6 lines 26-31; *"In Flow Chart view*

11, the process flow begins with a Start node, enters into the first Order nodes, and

flows out to Result nodes. After the results are entered, the process flow continues on to

a Flow Control node where the next step in the treatment is determined").

Regarding claim 45, Macrae/Campbell teaches that the programmed computer

provides a user interface to a knowledge base storing the clinical best practice workflow

(see Macrae column 2 lines 44-55; *"The display includes a plurality of graphic icon*

images, stored in the storage location, arranged on the display representing a medical

treatment plan").

Claim 46 recites a programmed computer having substantially the same limitations as the programmed computer of claim 1. Therefore, claim 46 is rejected under the same rationale.

Claim 47 recites a computer-implemented method having substantially the same limitations as the programmed computer of claim 1. Therefore, claim 47 is rejected under the same rationale.

Regarding claim 58, Macrae/Campbell teaches a programmed computer comprising a processor configured to assist a healthcare practitioner in diagnosing and treating patients by interacting with the healthcare practitioner during progression through a respective centrally-stored version of a clinical best practice workflow comprised of a plurality of interlinked steps (see Macrae column 1 lines 6-11; "*The present invention relates to providing graphic medical healthcare plans (protocols), and in particular a graphic user interface, for developing, viewing and implementing medical healthcare plans*"; see also Macrae column 8 lines 4-11; "*a physician may retrieve a template from the library that addresses a similar condition, modify the template as needed, and start the patient treatment using the modified template*"; see also Macrae column 31 lines 41-65; "*Every user may have their own library or link to a common library shared by others... Library items added at the top level are available to everyone within the network*"), and the programmed computer comprising:

a page including a map for assisting the healthcare practitioner to navigate the respective centrally-stored version of the clinical best practice workflow, the map comprising a plurality of patient care pathways, each comprising a series of a plurality of

interlinked nodes, wherein each node in the series has a unique relationship with a

respective step in the respective centrally-stored version of the clinical best practice

workflow (see Macrae Figure 1 and column 6 lines 26-31; "*In Flow Chart view 11, the

process flow begins with a Start node, enters into the first Order nodes, and flows out to

Result nodes. After the results are entered, the process flow continues on to a Flow

Control node where the next step in the treatment is determined*");

editing means for enabling the healthcare practitioner to edit at least some of the

nodes on the page (see Macrae Figure 1 and column 6 lines 14-25; "*FIG. 1 illustrates

an example of a Template Builder window with an open template*");

updating means arranged to update the plurality of interlinked steps of the

respective centrally-stored version of the clinical best practice workflow with any

corresponding changes made to the respective nodes on the page by the healthcare

practitioner (see Macrae column 9 lines 57 and 58; "*Edit button 119 edits the detail of

the selected order, including the order's result values when clicking*");

navigation means arranged to enable the healthcare practitioner to choose the

node to traverse next, and to permit the healthcare practitioner to traverse a rout across

the map that misses out one or more nodes from the series of the plurality of interlinked

nodes representing a currently traversed patient care pathway (see Macrae column 19

lines 56-60; "*To force the plan to branch down a specific path, regardless of the result

values and the flow control rules, a user opens the right-most active Flow Control node,

select the rule governing the desired path, and click the Execute button. The plan will

branch down the specified path*"; see also Macrae column 12 lines 36-40; "*The Flow

Control node contains the rules that determine which set of orders are followed. Flow

Control nodes are connected to one or more Order nodes. However, only one of the

Order nodes will be executed"); and

Electronic Patient Record Management System (EPRMS) management means

for communicating with an EPRMS and obtaining and presenting details of a selected

electronic patient record in a portion of the page (see Campbell column 14 lines 19-29;

"*When the user selects a screen for display, the patient data in the display is drawn*

from the current patient records on the server").

Claims 59-64 recite a programmed computer having substantially the same

limitations as the programmed computer of claims 35-39. Therefore, the claims are

rejected under the same rationale.

Regarding claim 82, Macrae/Campbell teaches a computer-implemented

method of constructing a graphical user interface for assisting a healthcare professional

in diagnosing and treating patients, the computer-implemented method comprising:

Collating, using a programmed computer, content regarding a clinical best

practice workflow (see Macrae column 7 lines 22-26; "*Before a user can create a*

template, treatment work flow must be defined; that is, the order in which treatment

activities are carried out for a given condition");

Recording, using a programmed computer, the content in a database as a series

of steps of a hierarchically structured clinical best practice workflow (see Macrae

column 16 lines 22-30; templates are created and saved);

automatically generating, using a programmed computer, a graphical

representation of the hierarchical clinical best practice workflow from the content

recorded in the database, which can be used to guide a healthcare practitioner

progressively through the clinical best practice workflow (see Macrae column 1 lines 6-

11; "*The present invention relates to providing graphic medical healthcare plans*

(protocols), and in particular a graphic user interface, for developing, viewing and

implementing medical healthcare plans");

enabling, using a programmed computer, the healthcare practitioner to choose

the node to traverse next, and to permit the healthcare practitioner to traverse a route

across the map that misses out one or more nodes from the series of the plurality of

interlinked nodes representing a currently traversed patient care pathway (see Macrae

column 19 lines 56-60; "*To force the plan to branch down a specific path, regardless of*

the result values and the flow control rules, a user opens the right-most active Flow

Control node, select the rule governing the desired path, and click the Execute button.

The plan will branch down the specified path"; see also Macrae column 12 lines 36-40;

"*The Flow Control node contains the rules that determine which set of orders are*

followed. Flow Control nodes are connected to one or more Order nodes. However, only

one of the Order nodes will be executed"); and

communicating, using a programmed computer, with an Electronic Patient

Record Management System (EPRMS) to obtain and present details of a selected

electronic patient record in a portion of the page (see Campbell column 14 lines 19-29;

"*When the user selects a screen for display, the patient data in the display is drawn*

from the current patient records on the server");

     wherein the graphical representation comprises a page including a map for

assisting the healthcare practitioner to navigate the stored clinical best practice

workflow, the map comprising a plurality of patient care pathways, each patient care

pathway conforming with best practice guidelines and comprising a series of a plurality

of interlinked nodes, wherein each node in the series has a unique relationship with a

respective step in the hierarchical clinical best practice workflow structure (see Macrae

Figure 1 and column 6 lines 26-31; "*In Flow Chart view 11, the process flow begins with*

a Start node, enters into the first Order nodes, and flows out to Result nodes. After the

results are entered, the process flow continues on to a Flow Control node where the

next step in the treatment is determined").

     Claims 83-85 recite a computer-implemented method having substantially the

same limitations as the programmed computer of claim 1. Therefore, the claims are

rejected under the same rationale.

     Regarding claim 87, Macrae/Campbell teaches that said clinical information is

revealed on the page by selection of the node itself within the programmed computer by

the healthcare practitioner (see Figure 14 and column 10 lines 50-55; "*Double-clicking*

Results node Re1 presents Result Node detail box 140").

     Regarding claim 88, Macrae/Campbell teaches that selective interaction with

the node by the healthcare practitioner comprises interaction between an end-user

navigational tool and the icon (see Macrae Figure 14 and column 10 lines 50-55;

"*Double-clicking Results node Re1 presents Result Node detail box 140*").

Regarding claim 89, Macrae/Campbell teaches that the graphical means is

arranged to graphically indicate previously executed steps in the best practice workflow

to the healthcare practitioner (see Macrae column 19 lines 36-44; "*When a user takes a*

branch down a path that leads to a Plan node in the patient's chart, the Plan node is

highlighted in both the Flow Chart and the patient Chart views").

Regarding claim 90, Macrae/Campbell teaches that previously executed steps

in the best practice workflow are graphically indicated to the healthcare practitioner (see

Macrae column 19 lines 36-44; "*When a user takes a branch down a path that leads to*

a Plan node in the patient's chart, the Plan node is highlighted in both the Flow Chart

and the patient Chart views").

Regarding claim 91, Macrae/Campbell teaches interacting with a node

displaying a graphical indication that concealed clinical information relating to the step in

the stored best practice workflow associated with the node is available, thereby

revealing the concealed clinical information in use (see Macrae column 9 lines 38-41;

"*By double-clicking Order node Or1 in the triplet shown in FIG. 9 or 10. The Order Node*

Detail dialog box 110 appears showing the list of orders (i.e., content) in Order node

Or1").

Claim 92 recites a programmed computer having substantially the same

limitations as the programmed computer of claim 1. Therefore, claim 92 is rejected

under the same rationale.

Claims 8-10, 28-34, and 38 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Macrae (5,786,816) *supra*, Campbell (6,047,259) *supra*, and DeBusk

et al. (hereinafter DeBusk), United States Patent 6,314,556.

Regarding claim 8, Macrae/Campbell teaches every limitation of claim 8 except

means for converting the entered data into a classification code representing that data.

The use of standard classification codes was well known in the healthcare industry at

the time the invention was made. DeBusk mentions the use of standardized codes

within his healthcare application (see DeBusk column 13 lines 28-43; *"the Procedure*

Attributes field 316 is provided which will allow the user to select standardized

procedure codes, such as the AMA IC9 code and description, for the procedure to be

represented by the pathway"). It would have been obvious to one of ordinary skill in the

art at the time the invention was made to use standardized classification codes in a

healthcare application in order to distinctly identify information.

Regarding claim 9, Macrae/Campbell/DeBusk teaches that the classification

code comprises a standard classification code describing a complete range of possible

data inputs relevant to the subject of the stored clinical best practice workflow (see

DeBusk column 13 lines 28-43).

Regarding claim 10, Macrae/Campbell/DeBusk teaches that the classification

code represents one of the group comprising a diagnosis, a symptom, an action, a

treatment and an operative procedure (see DeBusk column 13 lines 28-43).

Regarding claim 28, Macrae/Campbell/DeBusk teaches searching means for

searching an externally accessible knowledge base, the searching means being

arranged to convert a selected information topic (see Macrae column 32 lines 37-41;

"*The Find Item method 410 allows a client application to search through the library to*

find all the items that match the specified attributes and search criteria. The method

returns a container holding the matching library items, or actually references to the

items") into a predetermined classification code representing that topic and to transmit

that classification code within an information request to the knowledge base for relevant

information contained therein (see DeBusk column 13 lines 44-59; "*This function is*

provided with a database search capability, by the Search button 318, which allows the

user to search a pre-configured procedure code database for the appropriate procedure

information").

Regarding claim 29, Macrae/Campbell/DeBusk teaches that the classification

code comprises a standard classification code describing a complete range of possible

data inputs relevant to the subject of the stored best practice workflow (see DeBusk

column 13 lines 28-43; "*the Procedure Attributes field 316 is provided which will allow*

the user to select standardized procedure codes, such as the AMA IC9 code and

description, for the procedure to be represented by the pathway").

Regarding claim 30, Macrae/Campbell/DeBusk teaches that the classification

code represents one of the group comprising a diagnosis, a symptom, an action, a

treatment and an operative procedure (see DeBusk column 13 lines 28-43; "*the*

Procedure Attributes field 316 is provided which will allow the user to select

standardized procedure codes, such as the AMA IC9 code and description, for the

procedure to be represented by the pathway").

Regarding claim 31, Macrae/Campbell/DeBusk teaches that the searching

means is arranged to receive a response to the information request and display the

results of the search to the healthcare practitioner (see Macrae column 32 lines 37-41;

"*The Find Item method 410 allows a client application to search through the library to*

find all the items that match the specified attributes and search criteria. The method

returns a container holding the matching library items, or actually references to the

items").

Regarding claim 32, Macrae/Campbell/DeBusk teaches that the searching

means is arranged to receive a response to the information request and use the

response to determine a relevant page of a plurality of pages for display to the

healthcare practitioner (see Macrae column 32 lines 37-41).

Regarding claim 33, Macrae/Campbell/DeBusk teaches that the searching

means is arranged to display a plurality of information topics to the healthcare

practitioner and to enable selection of at least some of these information topics, each

information topic being related to the current node location of the healthcare practitioner

within the current page (see Macrae column 32 lines 37-41).

Regarding claim 34, Macrae/Campbell/DeBusk teaches that the searching

means is arranged to enable the healthcare practitioner to enter additional information

topics not displayed by the searching means (see Macrae column 32 lines 37-41).

Regarding claim 38, Macrae/Campbell/DeBusk teaches that the editing means is arranged to enable the healthcare practitioner to add or edit a classification code associated with the contents of a node (see Macrae column 6 lines 14-25; "*FIG. 1 illustrates an example of a Template Builder window with an open template*", the Template Builder allows users to add any node and the contents of the added node).

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Campbell (6,047,259) *supra*, and Balint et al. (hereinafter Balint), United States Patent 5,542,024.

Regarding claim 17, Macrae/Campbell teaches every limitation of claim 17 except for a note recordal means for recording textual notes generated by the healthcare practitioner relating to a particular node, the note recordal means being arranged to link the note with the particular node such that the stored note is retrievable when the healthcare practitioner has navigated to that particular node. Balint teaches an expert system in which users can record textual notes that will also be visible to other users of the system (see Balint claims 21 and 22; "*means for creating a note data base record to be linked to a currently displayed decision node in the expert system in response to the selection of a write representative icon displayed by said Graphical User Interface*" and "*includes means to add a read representative icon to said Graphical User Interface display whenever one of said note data base records has been linked to the decision node of the knowledge record then being displayed*"). It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow

textual notes to be attached to workflow nodes in order to provide an intuitive method of knowledge exchange between users of the system.

Regarding claim 18, Macrae/Campbell/Balint teaches that the note recordal means is arranged to record a variation of the stored clinical best practice workflow at a particular node as determined by the healthcare practitioner (see Balint claims 21 and 22).

Regarding claim 19, Macrae/Campbell/Balint teaches feedback generation means for converting a note determined by the healthcare practitioner into a transmittable message and for transmitting the message to another healthcare practitioner having access to a version of the programmed computer (see Balint, Claims 21 and 22).

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae (5,786,816) *supra*, Campbell (6,047,259) *supra*, and Greenberg et al. (hereinafter Greenberg), United States Patent Application Publication 2004/0039602.

Regarding claim 25, Macrae/Campbell teaches every limitation of claim 25 except referral means for generating a referral message, the referral means being provided at a node and using information associated with the node to populate at least some of the referral message on selection by the healthcare practitioner. Greenberg teaches a computerized system that assists a healthcare professional in accessing patient medical record data, following clinical pathway protocols, and entering data (see Greenberg paragraph [0005]; "*the system helps to ensure that the patient is properly*

evaluated, all pertinent information is gathered, etc. and that all appropriate treatment

options are considered. Additionally, patient medical record data is available, and

examination data is recorded, at the point of care. Optionally, the system may store a

protocol database accessible by the examination and/or treatment modules to guide the

clinician through examination and treatment according to predefined protocols. For

example, these treatment protocols can be established on the basis of clinical

pathways, research protocols, or cost of care"). Greenberg also teaches that the

invention is capable of generating and storing referrals (see Greenberg paragraph

[0007]; *"The system is capable of generating medical and related records (collectively,*

"medical records"), such as examination notes, orders, bills, referral letters, etc., by

incorporating relevant data stored by the system into predefined templates, such as

Microsoft Word or Excel documents"). It would have been obvious to one of ordinary

skill in the art at the time the invention was made to generation, storing, and accessing

of referrals as taught by Greenberg in the invention of Macrae/Campbell so that all

relevant information about a patient is accessible from the same system.

      Regarding claim 26, Macrae//Campbell/Greenberg teaches that the referral

means comprises a graphical icon and selection by the healthcare practitioner

comprises interaction between a user navigational tool and the icon (see Figure 1,

Macrae's invention makes extensive use of icons for interaction and navigation).

      Regarding claim 27, Macrae/Campbell/Greenberg teaches that the referral

means is arranged to use information obtained from an electronic patient record to

populate automatically at least some of the referral message (see Greenberg paragraph

[0007]; "*The system is capable of generating medical and related records (collectively,*

"medical records"), such as examination notes, orders, bills, referral letters, etc., by

incorporating relevant data stored by the system into predefined templates, such as

Microsoft Word or Excel documents").

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macrae

(5,786,816) *supra*, Campbell (6,047,259) *supra*, and Huyn et al. (hereinafter Huyn),

United States Patent Application Publication 2002/0035486.

Regarding claim 86, Macrae/Campbell teaches every limitation of claim 86

except that the editing means is arranged such that its use by the healthcare

practitioner is restricted by permissions. Huyn teaches a computerized clinical

questionnaire system that makes use of permissions (see Huyn paragraph [0064];

"*once the user has submitted the response data, he or she cannot modify the data*

without permission from the questionnaire administrator"). It would have been obvious

to one of ordinary skill in the art at the time the invention was made to use permissions

as taught by Huyn to regulate the use of the invention taught by Macrae/Campbell to

prevent unauthorized changes from being made to the system.

Response to Arguments

Amendments made to claim 82 renders the previous objection to claim 82 moot.

Accordingly, the previous objection to claim 82 is withdrawn. However, a new objection

to claim 82 applies (see Claim Objections above).

Applicant asserts that 35 USC 112, First Paragraph rejection should be withdrawn. Examiner respectfully disagrees. Clarification of the 35 USC 112 rejection is provided above.

Applicant's arguments with respect to claims 1, 46, 47, 58, 82, and 92 have been considered but are moot in view of the new ground(s) of rejection. Campbell (6,047,259) *supra* discloses an Electronic Patient Record Management System (EPRMS), and it would have been reasonable to implement such a system in the invention of Macrae. It is noted that, as best understood, an EPRMS is not a specific product or standard, but rather describes any system for managing patient records electronically.

Applicant asserts that Macrae fails to disclose navigation means that permit the healthcare practitioner to traverse a route across the map that misses out one or more nodes from the series of the plurality of interlinked nodes representing a currently traversed care pathway. Examiner respectfully disagrees.

It is noted that as discussed above, the meaning of "misses out one or more nodes" is unclear and is being interpreted in the broadest reasonable interpretation in light of the specification. Macrae teaches branching down a specific path (see Macrae column 19 lines 56-66; "*To force the plan to branch down a specific path, regardless of the result values and the flow control rules, a user opens the right-most active Flow*

Control node, select the rule governing the desired path, and click the Execute button.

The plan will branch down the specified path."). Doing so would "miss out one or more

nodes", as recited in the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Stephen Alvesteffer whose telephone number is

(571)270-1295. The examiner can normally be reached on Monday-Friday 9:30AM-

6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, William Bashore can be reached on (571)272-4088. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen Alvesteffer

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